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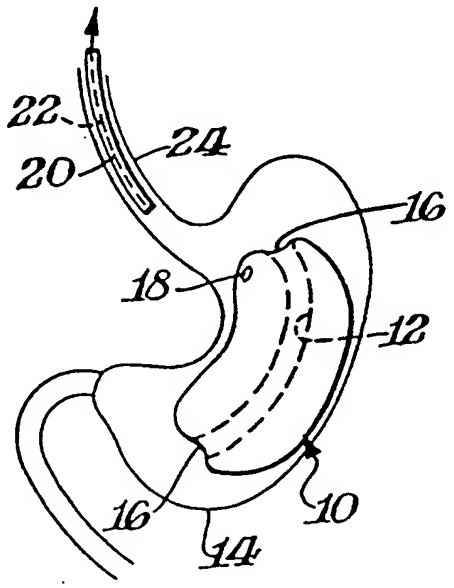
(54) Stomach insert for treating obesity.

(57) A stomach insert for treating obesity in humans by reducing the stomach volume comprises a flexible, inflatable balloon (10) which, in use, is free floating and unattached in the stomach (14), the balloon being inflatable to reduce the stomach volume of a person being treated. At least a portion of the balloon (10) has a self-sealing substance (18) to facilitate puncture thereof with insufflation tube (22) through which the balloon is inflated and to facilitate sealing of the puncture upon removal of the insufflation tube (22). The insert is used by introducing into the stomach (14) a stomach tube (20) having therein the balloon (10) releasably attached to the insufflation tube (22). The balloon (10) is urged out of the stomach tube (20) and inflated in the stomach (14). The stomach tube (20) and the insufflation tube are then removed.



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STOMACH INSERT FOR TREATING OBESITY

The present invention relates to the reduction of appetite e.g. for the treatment of obesity, in humans, and more particularly to both apparatus and method for curbing the appetite of persons (such as those being treated for obesity). Of course, the invention envisages the use of the apparatus for curbing appetite in cases other than clinical obesity, e.g. where weight loss is desired for cosmetic reasons.

Extreme obesity is a major illness in the United States and other countries. Its complications include hypertension, diabetes, coronary artery disease, stroke, congestive heart failure, venous disease, multiple orthopedic problems and pulmonary insufficiency with markedly decreased life expectancy. Medical management including dietary, psychotherapy, medications and behavioral modification techniques has yielded extremely poor results in multiple trials. Several surgical techniques have been tried which have bypassed the absorptive surface of the small intestine or have been aimed at reducing the stomach size by either partition or bypass. These procedures have been proven both hazardous to perform in morbidly obese patients and have been fraught with numerous life-threatening postoperative complications. Moreover such operative procedures are often difficult to reverse.

Non-surgical approaches for the treatment of obesity include voluntary dieting which is often unsuccessful since most persons do not possess sufficient willpower to limit the intake of food. Other approaches include the use of stomach fillers such as methyl cellulose, often taken in the form of tablets. The methyl cellulose expands in the stomach leaving the person with a filled-up feeling. Also, inflatable bag and tube combinations

have been proposed wherein the bag is swallowed into the stomach and the tube attached thereto is used to periodically inflate the bag, particularly just prior to mealtime or during the meal. Once the person has eaten, the bag can be deflated all at once, or it can be deflated gradually over a period of a few hours so as to simulate the condition of digestion occurring and the gradual reduction of stomach contents.

U.S. Patent 4,133,315 granted January 9, 1979 discloses such an inflatable bag and tube combination. The tubing remains attached to the bag and inside the esophagus of the person being treated. These tubes are often the cause of erosions and ulcerations of the esophagus. This patent also discloses a gastrotomy method wherein the permanently attached tube used to distend the stomach bag extends through an opening in the stomach wall as well as an opening in the abdomen.

Also, U.S. Patent 4,246,893 granted January 27, 1981 discloses an inflatable bag and tube combination which is surgically positioned outside and adjacent to the stomach. Upon inflation of the bag the upper abdomen is distended and the stomach compressed to thereby produce a sense of satiety which reduces the person's desire to ingest food.

Hence, reducing the size of the gastric compartment has been shown to induce weight loss in a significant percentage of people, and the present invention is aimed at a device which non-operatively reduces the size of the gastric compartment and which is easily removed.

Accordingly, it is an object of the present invention to curb a person's appetite in a manner which is safe, convenient and effective.

In accordance with the present invention, a stomach insert for treating obesity in humans by reducing the stomach volume comprises a flexible, free-floating and unattached, inflatable balloon, the balloon being inflatable to a volume effective to reduce the stomach volume of a person being treated. At least a portion of the balloon has a self-sealing substance to facilitate puncture thereof with insufflation means through which the balloon is inflated and to facilitate sealing of the puncture upon removal of the insufflation means.

Preferably, the stomach balloon has an inflated volume of approximately 200 to 800 cc., and the material from which it is made is both soft and flexible, having significant strength to resist over-inflation.

The method for treating obesity in humans according to the present invention comprises the steps of assembling a deflated stomach balloon with an insufflation tube releasably attached thereto inside a standard stomach tube. Thereafter the stomach tube is introduced through the mouth and into the stomach, and the balloon is urged out of the stomach tube into the stomach compartment. The attached insufflation tube is then used to inflate the balloon with a given amount of fluid. Finally, the insufflation tube is detached from the inflated balloon and along

with the stomach tube removed from the body of the person. Usually the balloon is inflated to a volume approximately 80% of the stomach volume.

The balloon may be removed from the stomach by introducing extraction means through the mouth and into the stomach, grasping and puncturing the balloon with the extraction means, and then withdrawing the deflated balloon out of the stomach and through the mouth. The extraction means may include a fiberoptic gastroscope with needle biopsy forceps.

Also, an assembly is provided comprising a stomach tube having a slit at the inner end thereof. A deflated stomach balloon is inside the tube at the inner end and a releasable drawstring closes the tube at the slit. Once the tube is in the stomach, the drawstring is removed and the balloon inflated. The balloon is easily separated from the tube as the tube spreads apart at the slit.

The present invention is further described by way of example only with reference to the accompanying drawings wherein similar reference numerals refer to similar parts and in which:

Figure 1 is a side elevational view of a stomach tube according to the present invention partially broken away to show details of the deflated balloon and its insufflation tube;

Figure 2 is a schematic side elevational view illustrating the balloon outside the stomach tube and partially inflated into the stomach;

Figure 3 is a schematic side elevational view of the balloon fully inflated inside the stomach with the insufflation tube detached from the balloon and both tubes being withdrawn from the person;

Figure 4 is a cross-sectional side elevational view of the fully inflated balloon shown in Figure 3;

Figure 5 is a schematic side elevational view of a fiber-optic gastroscope with needle biopsy forceps extending therefrom in the process of puncturing and removing the balloon from the stomach;

Figure 6 is a schematic side elevational view similar to Figure 5 with the balloon fully deflated and ready for removal;

Figure 7 is a schematic side elevational view similar to Figure 3 but illustrating an alternate embodiment of the stomach balloon;

Figure 8 is a cross-sectional side elevational view similar to Figure 4 illustrating the stomach balloon of Figure 7;

Figure 9 is a side elevational view of an alternate stomach tube according to the present invention with the deflated balloon and its insufflation tube disposed therein;

Figure 10 is a schematic side elevational view of the stomach tube of Figure 9 about to enter the stomach; and

Figure 11 is a view similar to Figure 10 with the balloon partially inflated inside the stomach.

Referring in more particularity to the drawings, Figures 1-6 herein illustrate a stomach implant or insert for treating obesity in humans by reducing the stomach volume. Specifically, the stomach insert comprises a flexible torus-shaped inflatable balloon 10 having a central opening 12 extending therethrough. The balloon may be fabricated from medical grade rubber or synthetic rubber-like material, one criterion being that such material be impervious so that the balloon is capable of holding a charge of air or other fluid. Obviously, the material selected must be capable of surviving in the gastric compartment,

and not dissolve or disintegrate or otherwise give off material, or absorb (take in). It should be soft and flexible having significant dynamic strength to resist over-inflation. As such, the finished product will inflate to the manufactured shape and not further. Morevoer, the finished product may be formed from a flat sheet of material and fastened together by solvent, heat, or RF welding techniques. One specific material is TUFTANE, polyester base, thermoplastic, polyurethane film manufactured by the Lord Corp.

As explained more fully below, the central opening 12 provides a passageway for solids and liquids as they pass through the stomach cavity 14. As shown best in Figure 4, the central opening 12 includes flared outer ends 16 that function to provide wide entrances to the central opening.

Continuing, the balloon 10 includes an injection site 18 fabricated from any self-sealing substance such as used in the injection site of standard intravenous tubing. The injection site 18 serves as a location for inflation of the balloon 10, and the balloon is sized so that its inflated volume is approximately 200 to 800 cc.

A standard levine or stomach tube 20 is utilized to position the balloon 10 inside the stomach. Also, prior to positioning the balloon inside the stomach, an insufflation tube 22 in the form of small bore polyethylene tubing is attached to the deflated balloon. In this regard the free end of the insufflation tube may carry a needle 26 which punctures the balloon at the injection site 18. As shown best in Figure 1, the deflated

stomach balloon 10 with the insufflation tube 22 attached thereto are stored inside the stomach tube 20 just prior to introducing the stomach tube through the mouth and into the stomach of the person being treated for obesity. The procedure is as follows.

Once the components are assembled as shown in Figure 1, the stomach tube is fed through the mouth and esophagus 24 into the stomach cavity 14. Next, the insufflation tube 22 is urged inwardly relative to the stomach tube 20 to thereby position the deflated balloon 10 inside the stomach. Air or another fluid is then introduced into the balloon 10 via the insufflation tube 22, as shown in Figure 2. After the balloon is inflated to approximately 80% of the stomach volume, the needle end 26 of the insufflation tube is removed from the injection site 18 which self-seals after such removal. The needle 26 is then housed inside the stomach tube and the stomach tube then withdrawn from the body of the person leaving a free-floating and unattached balloon.

The inflated bag is positioned as shown in Figure 3 with the central opening therein serving as a passageway through the stomach for both liquids and solids. Also, since the balloon is free-floating liquid and solid foods pass around the exterior surface of the balloon between that surface and the interior of the stomach wall. As noted above, the balloon is inflated to a volume of approximately 80% of the stomach volume and this phase of the procedure may be accomplished with the aid of x-ray examination, for example. The balloon remains in the stomach for the period the person is being treated for obesity, perhaps a period of three months or more, and it functions to reduce the volume size of the stomach and thereby curb the appetite of the person being treated for obesity.

Upon completion of the treatment, the balloon is easily removed from the stomach by means of a fiberoptic gastroscope 28 with needle biopsy forceps 30. As shown in Figure 5, the needle biopsy forceps grasp and puncture the balloon 10, and once the balloon is fully deflated it is simply drawn out of the stomach into the esophagus and out through the mouth of the person being treated.

Figures 7 and 8 illustrate an alternative embodiment of the invention that includes a stomach insert or balloon 10A similar in all respects to balloon 10 except for the absence of the central opening or passageway. Balloon 10A has an oblong shape and includes an injection site 18A for the same purpose as site 18 of insert 10. The insert 10A is made of the same materials as insert 10. Also, it is positioned in the stomach, inflated, and removed in the same manner. In use, the balloon insert 10A is free-floating in the stomach compartment and unattached.

Figures 9-11 illustrate an alternative embodiment of the stomach tube similar to the levine tube but in this case a modified lavacuator tube 20A. Tube 20A has a longitudinal slit 32 extending from the inner end thereof upwardly a short distance about 2 to 5 inches. Pairs of small openings 34 are arranged on opposite sides of the slit 32, and a loop 36 extends through each pair of openings to provide an eyelet for reasons explained below.

In use, the deflated balloon, either 10 or 10A, is positioned inside tube 20A at the end thereof where the slit 32 is located, the insufflation tube 22 being attached to the balloon. Next, a drawstring 38 is threaded through the loops 34 in zig-zag

fashion from the end of tube 20A upwardly and into the interior of the tube at the other end of the slit. The drawstring extends through the tube to the outer free end thereof, and when tensioned, it closes the tube at the slit. At the inner end of tube 20A, string 38 extends several times through the end loops 36 to thereby provide a mild resistance when the string is tensioned to close the slit. However, such end connection 40 must be loose enough whereby the string may be withdrawn from the loops when slightly more tension is applied.

After the assembled tube 20A is positioned inside the stomach 14, tension is applied to the outside free end of drawstring 38 to remove it from the eyelet loops 36 and thereby allow tube 20A to open at the slit 32. Next, air or another fluid is introduced into the balloon via the insufflation tube 22. As the balloon increases in size it spreads apart stomach tube 20A at the slit thereof, as shown in Figure 11. When the balloon is fully inflated, insufflation tube 22 is easily detached by holding tube 20A and pulling on the free outside end of the insufflation tube. The balloon is urged against tube 20A but its inflated size prevents it from being drawn into the tube. Once the insufflation tube is detached, both it and the stomach tube are removed and the balloon freely floats in the stomach.

CLAIMS:

1. A stomach insert for treating obesity in humans by reducing the stomach volume comprising a flexible, inflatable balloon which in use is free-floating and unattached, the balloon being inflatable to a volume effective to reduce the stomach volume of a person being treated, at least a portion of the balloon having a self-sealing substance to facilitate puncture thereof with insufflation means through which the balloon is inflated and to facilitate sealing of the puncture upon removal of the insufflation means.

2. A stomach insert as claimed in Claim 1 wherein the balloon has an inflated volume of approximately 200 to 800 cc.

3. A stomach insert as claimed in Claim 1 or Claim 2 wherein the balloon is fabricated from soft and flexible material having significant dynamic strength to resist overinflation.

4. A stomach insert as claimed in any one of the preceding claims wherein the balloon has a passageway therethrough, through which the stomach contents may pass.

5. A method for curbing appetite in humans comprising the steps of assembling a deflated stomach balloon with an insufflation tube releasably attached thereto inside a standard stomach tube, thereafter introducing the stomach tube through the mouth and into the stomach, urging the balloon out of the stomach tube and into the stomach, inflating the balloon through the insufflation tube with a given amount of fluid to increase the volume thereof while enabling the inflated balloon to freely float within the stomach, and then removing the stomach tube and the insufflation tube from the stomach and out through the mouth whereby the inflated balloon is unattached and free to float within the stomach.

6. A method as claimed in Claim 5 wherein the balloon is inflated to a volume approximately 80% of the stomach volume.

7. A method as claimed in Claim 5 or Claim 6 including the step of removing the balloon from the stomach by introducing extraction means through the mouth and into the stomach, grasping and puncturing the balloon with the extraction means, and then withdrawing the deflated balloon out of the stomach

and through the mouth.

8. A method as claimed in Claim 7 wherein the extraction means includes a fiberoptic gastroscope with needle biopsy forceps.

9. An assembly comprising a stomach tube having a longitudinal slit at the inner end thereof, a deflated stomach balloon inside the tube at the inner end thereof, insufflation means attached to the balloon and extending through the stomach tube, and drawstring means releasably closing the inside end of the stomach tube at the slit whereby upon removal of the drawstring and inflation of the balloon the balloon is easily separated from the stomach tube as the tube spreads apart at the slit.

10. An assembly as claimed in Claim 9 wherein the balloon is as claimed in any one of Claims 1 to 4.

Fig.1.

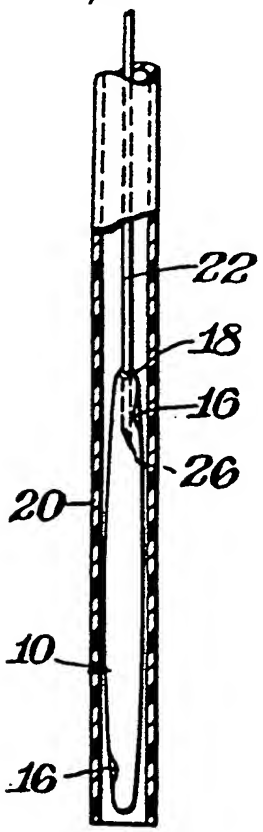


Fig.2.

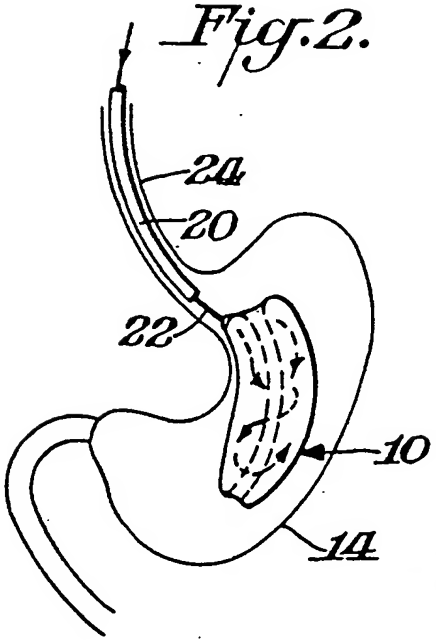


Fig.4.

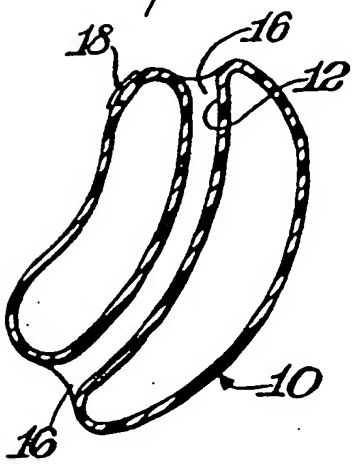


Fig.3.

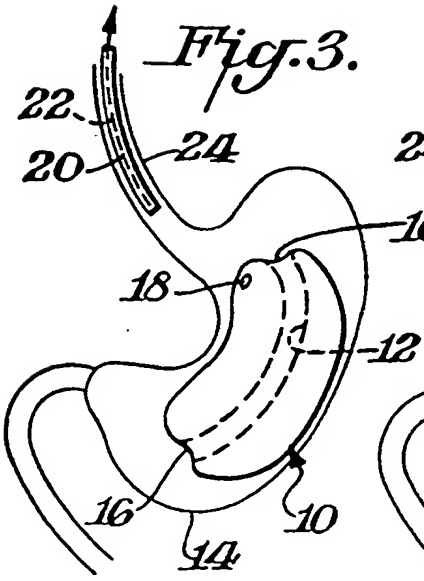


Fig.5.

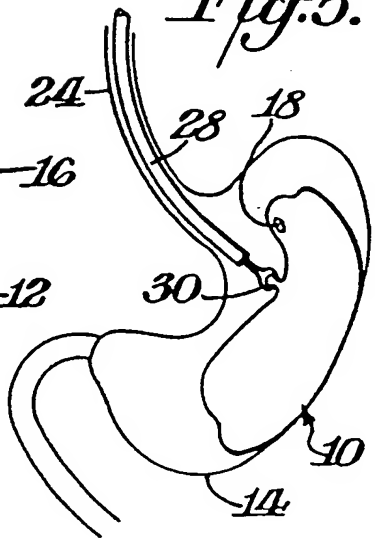


Fig.6.

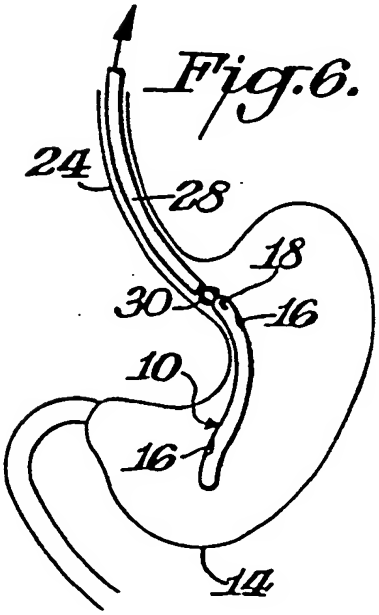


Fig. 7.

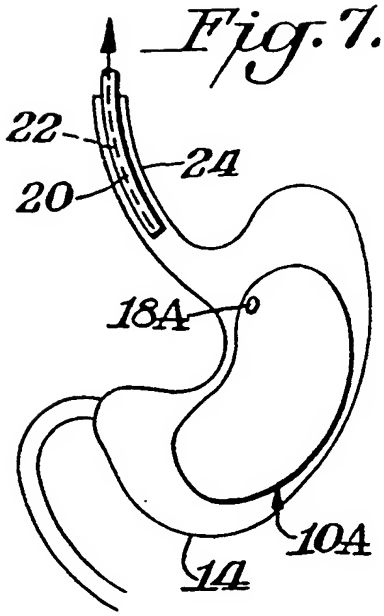


Fig. 8.

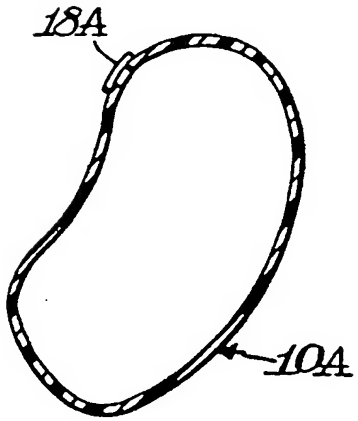


Fig. 9.

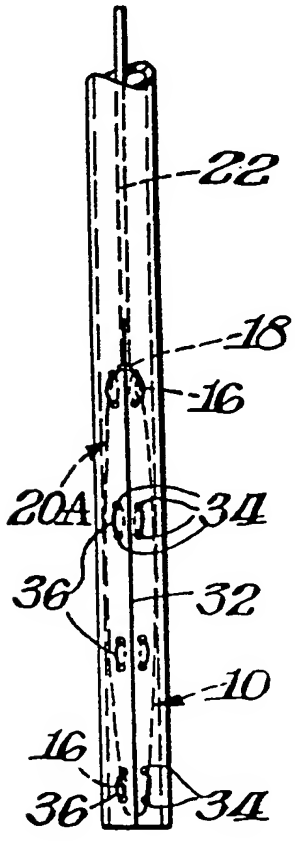


Fig. 10.

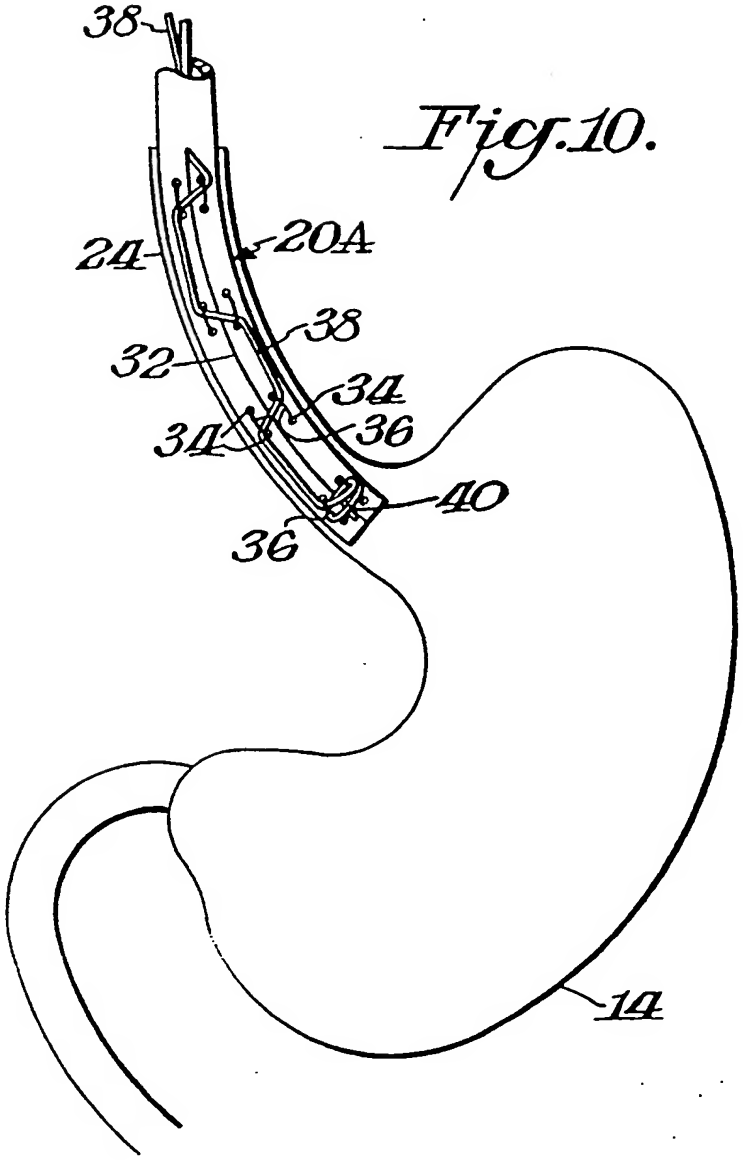
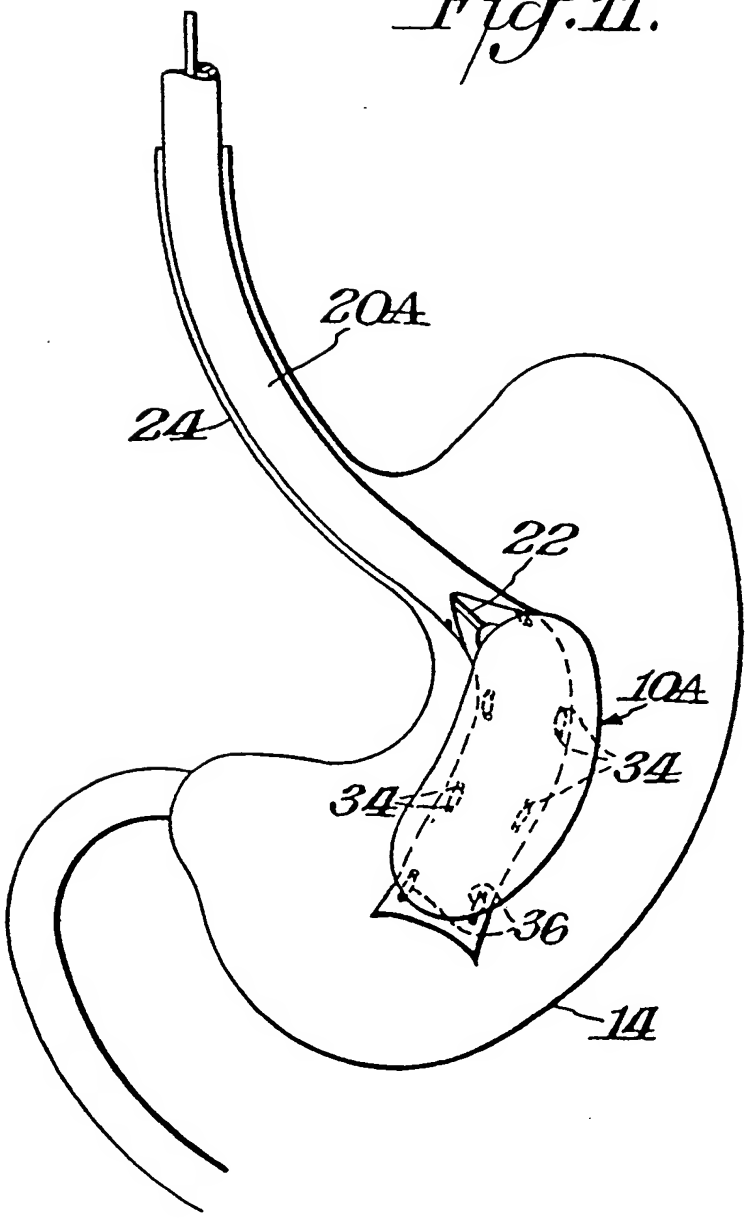


Fig.11.



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EUROPEAN SEARCH REPORT

0137878
Application number

EP 83 30 7026

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.4)
E,X	US-A-4 416 267 (GARREN et al.) *The whole document*	1-8	A 61 F 5/00
X	DE-A-3 227 585 (WÖRNER) *The whole document*	1-3,5,6	
Y		4	
Y	WO-A-8 000 007 (ROCKEY) *Pages 2,3; figures 1,4*	4	
X	EP-A-0 086 862 (McCLOY) *Pages 1-6; figure 1*	1-3,5-8	
A		9,10	TECHNICAL FIELDS SEARCHED (Int. Cl.4) A 61 F A 61 B

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
THE HAGUE	28-11-1984	LOWE D.

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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& : member of the same patent family, corresponding document

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